

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 7:

A61F 2/16

(11) International Publication Number:

WO 00/27314

A1

(43) International Publication Date:

18 May 2000 (18.05.00)

(21) International Application Number:

PCT/US99/24921

(22) International Filing Date:

21 October 1999 (21.10.99)

(30) Priority Data:

09/186,720

5 November 1998 (05.11.98)

US

(71) Applicant: BAUSCH & LOMB SURGICAL, INC. [US/US]; 555 West Arrow Highway, Claremont, CA 91711 (US).

(72) Inventors: HOFFMANN, Laurent; 26741 Palora, Foothill Ranch, CA (US). ROSS, Mark, Wesley; 226 Cabrillo Street, Costa Mesa, CA 92627 (US). STENGER, Donald, Carroll; 550 South Golden Sky Lane, Anaheim Hills, CA 92807 (US).

(74) Agents: VACCA, Rita, D. et al.; Bausch & Lomb, Incorporated, One Bausch & Lomb Place, Rochester, NY 14604-2701 (81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published

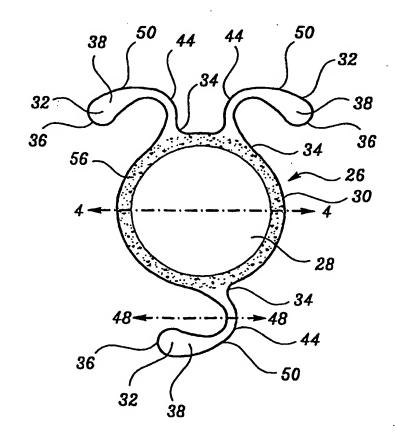
With international search report.

Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: FLEXIBLE INTRAOCULAR LENS

(57) Abstract

A refractive intraocular lens (26) including an optic portion (28) having an outer peripheral edge (30) and three or four balanced haptic elements (32). Each haptic element (32) is formed to have an inner portion (34) and outer tip (36) for supporting the optic portion (28) in a patient's eye. The inner portion (34) of each haptic element (32) is permanently connected to the outer peripheral edge (30) of the optic portion (28). Each haptic element (32) also includes a contact plate (38) and a transition portion (50), which extends between the contact plate (38) and the inner portion (34). Each haptic (32) is formed to have greater resistance to bending in a plane generally parallel to an eye's optical axis than in a plane (48-48) generally perpendicular to the eye's optical axis. The intraocular lens (26) is so designed to exhibit less than approximately 1.0 mm axial displacement of the optic portion along the eye's optical axis under a compression force suitable to effect a 1.0 mm in diameter compression of the intraocular lens (26).



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav	TM	Turkmenistan
BF	Burkina Faso	GR	Greece		Republic of Macedonia	TR	Turkey
BG	Bulgaria	HU	Hungary	ML	Mali	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MN	Mongolia	ŪA	Ukraine
BR	Brazil	IL	Israel	MR	Mauritania	υG	Uganda
BY	Belarus	IS	Iceland	MW	Malawi	US	United States of America
CA	Салада	ĪТ	Italy	MX	Mexico	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NE	Niger	VN	Viet Nam
CG	Congo	KE	Kenya	NL	Netherlands	YU	Yugoslavia
СН	Switzerland	KG	Kyrgyzstan	NO	Norway	zw	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's	NZ	New Zealand	2	Zamoub we
CM	Cameroon		Republic of Korea	PL	Poland		
CN	China	KR	Republic of Korea	PT	Portugal		
CU	Cuba	KZ	Kazakstan	RO	Romania		
CZ	Czech Republic	LC	Saint Lucia	RU	Russian Federation		
DE	Germany	LI	Liechtenstein	SD	Sudan		
DK	Denmark	LK	Sri Lanka	SE	Sweden		
EE	Estonia	LR	Liberia	SG	Singapore		·

FLEXIBLE INTRAOCULAR LENS

FIELD OF THE INVENTION

The present invention relates to intraocular lenses (IOLs) and a method for making and using the same. More particularly, the present invention relates to IOLs designed primarily for refractive correction in phakic eyes where the eye's natural lens remains intact. IOLs made in accordance with the present invention may also be used in aphakic eyes where a diseased natural lens is surgically removed, such as in the case of cataracts, and a method for producing and using the same.

BACKGROUND OF THE INVENTION

Visual acuity deficiencies such as myopia (nearsightedness), hyperopia (farsightedness) and presbiopia (age-related farsightedness) are typically corrected with use of refractive lenses such as spectacles or contact lenses. Although these types of lenses are effective in correcting a wearer's eyesight, many wearers consider the lenses inconvenient. The lenses must be located, worn at certain times, removed periodically and may be lost or misplaced. The lenses may also be dangerous or cumbersome if the wearer participates in athletic activities or suffers an impact in an area near the eyes.

The use of surgically implanted IOLs as a permanent form of refractive correction has been gaining in popularity. IOL implants have been used for years in aphakic eyes as replacements for diseased natural crystalline lenses that have been surgically removed from the eyes. Many different IOL designs have been developed over past years and proven successful for use in aphakic eyes. The successful IOL designs to date primarily include an optic portion with supports therefor, called haptics, connected to and surrounding at least part of the optic portion. The haptic portions of an IOL are designed to support the optic portion of the IOL in the lens capsule, anterior chamber or posterior chamber of an eye.

Commercially successful IOLs have been made from a variety of biocompatible materials, ranging from more rigid materials such as polymethylmethacrylate (PMMA) to softer, more flexible materials capable of being folded or compressed such as silicones, certain acrylics, and hydrogels. Haptic portions of the IOLs have been formed separately from the optic portion and later connected thereto through processes such as heat, physical staking and/or chemical bonding. Haptics have also been formed as an integral part of the optic portion in what is commonly referred to as "single-piece" IOLs.

Softer, more flexible IOLs have gained in popularity in recent years due to their ability to be compressed, folded, rolled or otherwise deformed. Such softer IOLs may be deformed prior to insertion thereof through an incision in the cornea of an eye. Following insertion of the IOL in an eye, the IOL returns

to its original pre-deformed shape due to the memory characteristics of the soft material. Softer, more flexible IOLs as just described may be implanted into an eye through an incision that is much smaller, i.e., 2.8 to 3.2 mm, than that necessary for more rigid IOLs, i.e., 4.8 to 6.0 mm. A larger incision is necessary for more rigid IOLs because the lens must be inserted through an incision in the cornea slightly larger than the diameter of the inflexible IOL optic portion. Accordingly, more rigid IOLs have become less popular in the market since larger incisions have been found to be associated with an increased incidence of postoperative complications, such as induced astigmatism.

After IOL implantation, both softer and more rigid IOLs are subject to compressive forces exerted on the outer edges thereof, which typically occur when an individual squints or rubs the eye. These compressive forces may result in decentration of the IOL and distortion of the visual image.

Compressive forces exerted on an IOL also tend to cause axial displacement of the IOL along the optical axis of an eye. Movement of an IOL along the optical axis of an eye has the potential to cause the IOL to contact and damage the delicate corneal endothelial cell layer of the eye. Also, IOLs of current designs, whether formed of either softer or more rigid materials, tend to deflect along the optical axis of an eye when the haptics are compressed. IOL manufacturers provide a wide range of IOL sizes to more precisely fit IOLs to each particular patient's eye size. Providing a wide range of IOL sizes is an

attempt to minimize the potential for axial displacement of the IOL along the optical axis of an eye.

Because of the noted shortcomings of current IOL designs, there is a need for IOLs designed to minimize axial displacement of the IOL optic portion along the optical axis of the eye when compressive forces are exerted against the outer edges thereof. By lessening an IOLs movement along the optical axis of an eye, more certain refractive correction may be achieved and the risk of endothelial cell layer damage may be reduced.

SUMMARY OF THE INVENTION

An intraocular lens (IOL) made in accordance with the present invention has an optic portion with an outer peripheral edge and either three or four haptic elements for supporting the optic portion in a patient's eye. A lens having three haptic elements is balanced having two spaced haptic elements formed on one edge of the optic and the third haptic element formed on an opposite edge of the optic. A lens having four haptic elements is balanced having two spaced haptic elements formed on one edge of the optic and two spaced haptic elements formed on an opposite edge of the optic. Each of the haptic elements has an inner portion and an outer portion with the inner portion being connected to the outer peripheral edge of the optic portion. Each haptic element includes a contact plate on the outer portion thereof. The contact plates are designed to engage an inner surface of a patient's eye.

Each haptic also has a central portion that extends between the contact plate and the inner portion. Within this central portion, each haptic element is designed to have greater resistance to bending in a plane generally parallel to the optical axis of an eye than in a plane generally perpendicular to the optical axis of an eye. By providing haptic elements with this type of flexibility characteristic, the present IOL fits eyes of varying sizes. The flexibility characteristic of the subject haptic elements relative to the optic portion eliminates unacceptable axial displacement of the optic portion along the optical axis when compressive forces are exerted against the haptic elements of the IOL.

Accordingly, it is an object of the present invention to provide intraocular lenses for use in phakic eyes.

Another object of the present invention is to provide intraocular lenses for use in phakic eyes, which fit a variety of eye sizes.

Another object of the present invention is to provide intraocular lenses for use in phakic eyes, which minimize axial displacement of the optic portions of the lenses along the optical axis of the eyes.

Another object of the present invention is to provide intraocular lenses for use in phakic eyes, which minimize damage to tissues in the interior of the eyes.

Still another object of the present invention is to provide intraocular lenses, which are resistant to decentration within the eyes.

These and other objectives and advantages of the present invention, some of which are specifically described and others that are not, will become apparent from the detailed description, drawings and claims that follow, wherein like features are designated by like numerals.

BRIEF DESCRIPTION OF THE DRAWINGS

FIGURE 1 is a schematic representation of the interior of a human eye including a natural lens and a refractive IOL implanted in the anterior chamber of the eye;

FIGURE 2 is a plan view of an IOL with three haptics made in accordance with the present invention;

FIGURE 3 is a side view of the IOL of Figure 2;

FIGURE 4 is a cross sectional view of the IOL of Figure 2 taken along line 4-4;

FIGURE 5 is a perspective view of the IOL of Figure 2;

FIGURE 6 is a perspective view of a contact plate of Figure 2 with sharper edges;

FIGURE 7 is a perspective view of a contact plate of Figure 2 with rounded edges;

FIGURE 8 is a side view of a haptic element of Figure 2 with a stiffening element;

FIGURE 9 is a plan view of an IOL with four haptics made in accordance with the present invention;

FIGURE 10 is a side view of the IOL of Figure 9; and FIGURE 11 is a perspective view of the IOL of Figure 9.

DETAILED DESCRIPTION OF THE INVENTION

Figure 1 illustrates a simplified diagram of an eye 10 showing landmark structures relevant to the implantation of an intraocular lens of the present invention. Eye 10 includes an optically clear comea 12 and an iris 14. A natural crystalline lens 16 and a retina 18 are located behind the iris 14 of eye 10. Eye 10 also includes anterior chamber 6 located in front of iris 14 and a posterior chamber 8 located between iris 14 and natural lens 16. IOLs of the present invention are preferably implanted in anterior chamber 6 to correct refractive errors while healthy natural lens 16 remains in place (phakic application). IOLs of the present invention may also be implanted in posterior chamber 8 or lens capsule 7 for use in aphakic eyes. When used in aphakic eyes, IOLs serve as replacements for surgically removed diseased natural lenses 16, such as for example following cataract surgeries. Eye 10 also includes an optical axis OA-OA that is an imaginary line that passes through the optical center 20 of anterior surface 22 and posterior surface 24 of lens 16. Optical axis OA-OA in the human eye 10 is generally perpendicular to a portion of cornea 12, natural lens 16 and retina 18.

The IOL of the present invention, illustrated in Figures 2 through 5 and 9 through 11 identified by reference numeral 26, is designed for implantation preferably in anterior chamber 6 of a patient's eye 10. However as mentioned above, IOL 26 may likewise be implanted in posterior chamber 8 or in the case

of an aphakic eye, in lens capsule 7. IOL 26 has an optic portion 28 with an outer peripheral edge 30. Preferably integrally formed on peripheral edge 30 of optic portion 28 are three or four separate haptic elements 32, each having an inner portion 34 and an outer tip 36. Inner portions 34 are preferably integrally formed with and permanently connected to outer peripheral edge 30 of optic portion 28. Each haptic element 32 also includes a broadened contact plate 38 designed to preferably engage inner surfaces 40 in anterior chamber 6. However, contact plates 38 are also suitable to engage inner surfaces 42 in posterior chamber 8 or inner surfaces 43 in lens capsule 7 of eye 10. Haptic elements 32 are preferably integrally formed on outer peripheral edge 30 of optic portion 28. Alternatively however, haptic elements 32 may be attached to optic portion 28 by staking, chemical polymerization or other methods known to those skilled in the art.

In accordance with the present invention, haptic elements 32 are designed so that when IOL 26 is implanted in a patient's eye 10 and held in place through compressive forces exerted by inner surfaces 40, 42 or 43 on contact plates 38 of haptic elements 32, haptic elements 32 flex so that contact plates 38 do not slide along surfaces 40, 42 or 43 in the eye 10. Sliding of contact plates 38 is avoided in the subject IOL 26 since the distance of slide of each individual contact plate 38 would have to be the same to maintain the centering of IOL 26 on optical axis OA-OA. Accordingly, haptic elements 32 are designed to flex in a plane generally parallel to that of optic portion 28 of

IOL 26 and generally perpendicular to that of optical axis OA-OA of eye 10. By designing this type of flexibility characteristic into haptic elements 32, IOL 26 may be manufactured in one or a few standard sizes and be a suitable fit for most sizes of patients' eyes 10. The flexibility characteristic of haptic elements 32 also minimizes axial displacement of optic portion 28 in a direction along optical axis OA-OA of eye 10. Compressive forces of differing magnitudes within the range of approximately 2 to 8 mN exerted against contact plates 38 of haptic elements 32 to effect approximately an overall 1.0 mm in diameter compression of IOL 26, such as that caused by differing eye sizes, results in less than approximately 1.0 mm, but more preferably less than approximately 0.5mm and most preferably less than approximately 0.3 mm axial displacement of optic portion 28 along optical axis OA-OA in an eye 10. Under like compressive forces, IOLs known in the art result in approximately 2.0 mm axial displacement of the optic portion along the optical axis in the eye, which may damage delicate tissues therein. The unique design of IOL 26 achieves significantly minimized axial displacement of optic portion 28 to protect the corneal endothelium 4 of eye 10 from damage when compressive forces are applied to eye 10. By minimizing axial displacement of IOL 26, harmful contact with corneal endothelium 4 is also minimized.

The flexibility characteristic of haptic elements 32 of IOL 26 as described above is achieved through the unique design thereof. IOL 26 has haptic elements 32 formed with a central portion 44 adjacent to inner portion 34

permanently connected to outer peripheral edge 30 of optic portion 28. As best illustrated in Figures 3 and 10, central portion 44 has a dimension in plane 46-46, generally parallel to optical axis OA-OA, equal to or greater than the same in plane 48-48 generally perpendicular to optical axis OA-OA best depicted in Figure 2 and 9. A transition portion 50, of significantly decreasing size in dimension in plane 46-46 extends from central portion 44 to broadened contact plate 38. Contact plates 38 are relatively flat with either rounded edges 52 depicted in Figure 7 for a smoother fit with inner surfaces 40, 42 or 43, or more defined, sharper edges 54 depicted in Figure 6 to provide a barrier to prevent cellular migration and growth.

The subject IOL 26 is preferably produced having an optic portion 28 approximately 4.5 to 9.0 mm, but preferably approximately 5.0 to 6.0 mm and most preferably 5.5 mm in diameter and approximately 0.5 mm to 1.0 mm, but preferably approximately 0.6 to 0.8 mm and most preferably 0.7 mm in thickness at peripheral edge 30. Haptic elements 32 extend in a "U-shaped" configuration and will increase or decrease in length depending upon the diameter of optic portion 28. As the diameter of optic portion 28 increases, the length of haptic elements 32 decrease. Likewise, as the diameter of optic portion 28 decreases, the length of haptic elements 32 increase. In general, haptic elements 32 are formed to be approximately 2.6 to 6.0 mm, but preferably approximately 3.4 to 5.0 mm and most preferably approximately 4.2 mm in length measuring from the center of inner portion 34 to the center of

outer tip 36. Haptic elements 32 are preferred to have a U-shaped configuration as illustrated in Figures 2 and 9 to allow radial deflection under compressive forces while outer tips 36 remain stationary. For purposes of the present invention, the U-shape of haptic element 32, i.e., the beam curve shape, relative to the width to thickness ratio, i.e., the aspect ratio, of haptic element 32 as described herein is critical to achieve suitable function. Central portion 44 of haptic element 32 is approximately 0.5 to 2.5 mm, but preferably approximately 1.0 to 2.0 mm and most preferably 1.6 mm in length; approximately 0.2 to 1.0 mm, but preferably approximately 0.3 to 0.7 mm and most preferably approximately 0.46 mm in thickness in plane 46-46 and approximately 0.2 to 0.7 mm, but preferably approximately 0.3 to 0.6 and most preferably approximately 0.43 mm in width in plane 48-48. Transition portion 50 is approximately 0.4 to 1.1 mm, but preferably approximately 0.5 to 1.0 mm and most preferably approximately 0.8 mm in length. Contact plate 38 is approximately 0.8 to 2.5 mm, but preferably approximately 1.0 to 2.2 mm and most preferably approximately 1.8 mm in length, approximately 0.05 to 0.5 mm, but preferably approximately 0.1 to 0.4 mm and most preferably approximately 0.3 mm in thickness and approximately 0.6 to 1.5 mm, but preferably approximately 0.8 to 1.2 mm and most preferably approximately 1.0 mm in width.

As provided through the dimensions of IOL 26 above, haptic elements 32 gradually change from being relatively thin in plane 46-46 at outer tip 36 to

being relatively thick at inner portion 34 and optic portion 22, with central portion 44 preferably exhibiting a thicker dimension in plane 46-46 than that of the width in plane 48-48. Haptic elements 32 of the subject design tend to flex into closer proximity with outer peripheral edge 30 when a compression force is exerted against contact plates 38 with minimal axial displacement along optical axis OA-OA. When IOL 26 is used as a refractive lens, a stable, reliable refractive correction is provided.

The desired flexibility characteristic of haptic elements 32 of IOL 26 may likewise be achieved or enhanced by incorporating a stiffening element 60, in the shape of a ribbon, in one or more haptic elements 32, as illustrated in Figure 8. Stiffening element 60 may be positioned in haptic element 32 so that flat face 62 is oriented parallel to the dimension 46-46. Stiffening element 60 functions in a manner similar to that of an I-beam in construction to prevent axial displacement along optical axis OA-OA when compressive force is applied to contact plates 38.

. · 🖔

Stiffening element 60 is formed of a less flexible material than that of IOL 26. Suitable materials for stiffening element 60 include but are not limited to polyimides, polyolefins, high-density polyethylenes, polyesters, nylons, metals or any biocompatible material with suitable stiffening characteristics. Stiffening element 60 may be used in conjunction with haptic elements 32 described above or in cases where a thinner haptic design is desired while still achieving the desired flexibility characteristics.

Suitable materials for the production of the subject IOL 26 include but are not limited to foldable or compressible materials, such as silicone polymers, hydrocarbon and fluorocarbon polymers, hydrogels, soft acrylic polymers, polyesters, polyamides, polyurethane, silicone polymers with hydrophilic monomer units, fluorine-containing polysiloxane elastomers and combinations thereof. The preferred material for the production of IOL 26 of the present invention is a hydrogel made from 2-hydroxyethyl methacrylate (HEMA) and 6hydroxyhexyl methacrylate (HOHEXMA), i.e., poly(HEMA-co-HOHEXMA). Poly(HEMA-co-HOHEXMA) is the preferred material for the manufacture of IOL26 due to its equilibrium water content of approximately 18 percent by weight, and high refractive index of approximately 1.474, which is greater than that of the aqueous humor of the eye, i.e., 1.33. A high refractive index is a desirable feature in the production of IOLs to impart high optical power with a minimum of optic thickness. By using a material with a high refractive index, visual acuity deficiencies may be corrected using a thinner IOL. A thin IOL, such as that of IOL 26, is particularly desirable in phakic applications to minimize potentially harmful contact between the IOL and iris 14 and corneal endothelium 4. Poly(HEMA-co-HOHEXMA) is also a desirable material in the production of IOLs 26 due to its mechanical strength, which is suitable to withstand considerable physical manipulation. Poly(HEMA-co-HOHEXMA) also has desirable memory properties suitable for IOL use. IOLs manufactured from a material possessing good memory properties such as thos of

poly(HEMA-<u>co</u>-HOHEXMA) unfold in a controlled manner in an eye, rather than explosively, to its predetermined shape. Explosive unfolding of IOLs is undesirable due to potential damage to delicate tissues within the eye. Poly(HEMA-<u>co</u>-HOHEXMA) also has dimensional stability in the eye.

Although the teachings of the present invention are preferably applied to soft or foldable IOLs formed of a foldable or compressible material, the same may also be applied to harder, less flexible lenses formed of a relatively rigid material such as polymethylmethacrylate (PMMA) having flexible haptics formed either of the same or a different material.

Optic portion 28 of IOL 26 can be a positive powered lens from 0 to approximately +40 diopters or a negative powered lens from 0 to approximately -30 diopters. Optic portion 28 may be biconvex, plano-convex, plano-concave, biconcave or concave-convex (meniscus), depending upon the power required to achieve the appropriate central and peripheral thickness for efficient handling.

Optic portion 28 of the subject IOL 26 may optionally be formed with a glare reduction zone 56 of approximately 0.25 to 0.75 mm but more preferably approximately 0.3 to 0.6 mm and most preferably 0.5 mm in width adjacent outer peripheral edge 30 for reducing glare when outer peripheral edge 30 of IOL 26 is struck by light entering eye10 during high light or at other times when pupil 58 is dilated. Glare reduction zone 56 is typically fabricated of the same

material as optic portion 28, but may be opaque, colored or patterned in a conventional manner to block or diffuse light in plane with optical axis OA-OA.

Subject IOL 26 is preferably manufactured by first producing discs from a material of choice as described in U.S. Patent Nos. 5,217,491 and 5,326,506 each incorporated herein in its entirety by reference. IOL 26 may then be machined from the material discs in a conventional manner. Once machined, IOL 26 may be polished, cleaned, sterilized and packaged by a conventional method known to those skilled in the art.

Subject IOL 26 is used in eye 10 by creating an incision in cornea 12, inserting IOL 26 in either anterior chamber 6 or posterior chamber 8 and closing the incision. Alternatively, IOL 26 may be used in eye 10 by creating an incision in cornea 12 and capsule 7, removing natural lens 16, inserting IOL 26 in capsule 7 and closing the incision.

IOL 26 of the present invention provides for a refractive lens suitable for use in lens capsule 7 or posterior chamber 8, but most preferably for use in anterior chamber 6 of eye 10. IOL 26 has haptic elements 32 with flexibility characteristics that minimize axial displacement along optical axis OA-OA of eye 10 thereby preventing decentration of IOL 26, distortion of vision and damage to corneal endothelium 4. IOL 26, having the flexibility characteristics described herein is also advantageous because one or a few lens sizes suitably fit eyes 10 of most sizes. By providing a "universal" lens such as that of the present invention, clinical risks to patients due to improperly sized lenses

are minimized. Such clinical risks minimized include pupil ovalization, corneal endothelium damage and poor fixation. Likewise, manufacturers' need to produce IOLs of many sizes to fit eyes of many sizes is eliminated, thus reducing production and inventory costs associated therewith.

Ophthalmologists also benefit from subject IOL 26 in that time is saved by eliminating the need to determine each patient's eye size and costs associated

While there is shown and described herein certain specific embodiments of the present invention, it will be manifest to those skilled in the art that various modifications may be made without departing from the spirit and scope of the underlying inventive concept and that the same is not limited to the particular forms herein shown and described except insofar as indicated by the scope of the appended claims.

with maintaining large inventories of varying sized lenses.

We claim:

 An intraocular lens to be implanted within an eye generally perpendicular to the eye's optical axis comprising:

an outer peripheral edge defining an optic portion, and three or four haptic elements permanently connected to the outer peripheral edge,

whereby a compressive force sufficient to effect a 1.0 mm in diameter compression of said lens results in less than approximately 1.0 mm of axial displacement of said optic portion along the eye's optical axis.

2. An intraocular lens to be implanted within an eye generally perpendicular to the eye's optical axis comprising:

an outer peripheral edge defining an optic portion, and three or four haptic elements permanently connected to the outer peripheral edge,

whereby a compressive force sufficient to effect a 1.0 mm in diameter compression of said lens results in less than approximately 0.5 mm of axial displacement of said optic portion along the eye's optical axis.

3. An intraocular lens to be implanted within an eye generally perpendicular to the eye's optical axis comprising:

an outer peripheral edge defining an optic portion, and three or four haptic elements permanently connected to the outer peripheral edge,

whereby a compressive force sufficient to effect a 1.0 mm in diameter compression of said lens results in less than approximately 0.3 mm of axial displacement of said optic portion along the eye's optical axis.

- 4. The intraocular lens of claim 1, 2 or 3 wherein the haptic elements and the optic portion are both formed of a foldable or compressible material.
- 5. The intraocular lens of claim 1, 2 or 3 wherein said lens is formed from a material selected from the group consisting of silicone polymers, hydrocarbon and fluorocarbon polymers, hydrogels, soft acrylic polymers, polyester, polyamides, polyurethane, silicone polymers with hydrophilic monomer units, fluorine-containing polysiloxane elastomers and combinations thereof.

6. The intraocular lens of claim 1, 2 or 3 wherein said lens is formed from a hydrogel material.

- 7. The intraocular lens of claim 1, 2 or 3 wherein said lens is formed from a hydrogel material which is 18 percent by weight water.
- 8. The intraocular lens of claim 1, 2 or 3 wherein said lens is formed from poly(HEMA-co-HOHEXMA).
- 9. The intraocular lens of claim 1, 2 or 3 wherein said lens is formed from a material having a refractive index above 1.33.
- 10. The intraocular lens of claim 1, 2 or 3 wherein said lens is formed from an acrylic material.
- 11. The intraocular lens of claim 1, 2 or 3 wherein said lens is formed from a silicone material.
- 12. The intraocular lens of claim 1, 2 or 3 wherein said haptic elements are dimensioned to be equal to or less in a plane generally perpendicular to the eye's optical axis than in a plane generally parallel to the eye's optical axis.

13. The intraocular lens of claim 1, 2 or 3 wherein a glare reduction zone is formed adjacent to the outer peripheral edge of the optic portion.

- 14. The intraocular lens of claim 1, 2 or 3 wherein one or more of said haptic elements includes a stiffening element having a greater resistance to bending in a plane generally parallel to an eye's optical axis than in a plane generally perpendicular to the eye's optical axis.
- 15. The intraocular lens of claim 1, 2 or 3 wherein the haptic element includes a stiffening element formed from a material selected from the group consisting of polyimide, polyolefin, high-density polyester, nylon and metal.
- 16. A method of manufacturing the intraocular lens of claim 1, 2 or 3 comprising:

forming a disk of a suitable material, and machining said lens from said disk.

17. A method of using the intraocular lens of claim 1, 2 or 3 comprising:

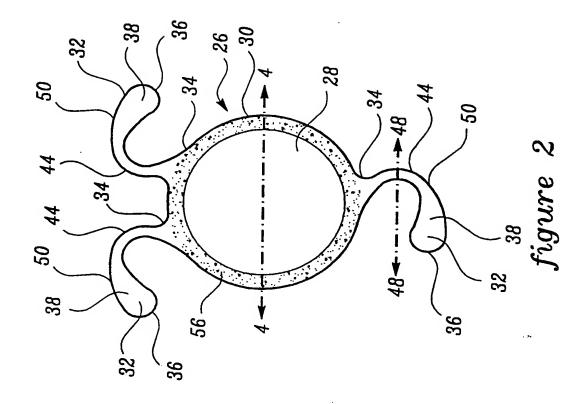
creating an incision in a comea of an eye, and inserting said intraocular lens in an anterior chamber of said eye.

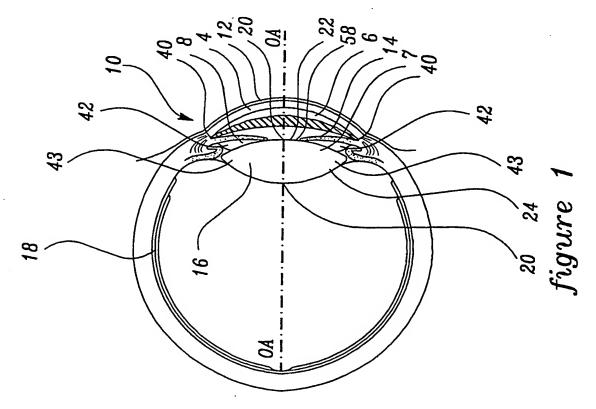
18. A method of using the intraocular lens of claim 1, 2 or 3 comprising :

creating an incision in a comea of an eye, and inserting said intraocular lens in a posterior chamber of said eye.

19. A method of using the intraocular lens of claim 1,2 or 3 comprising :

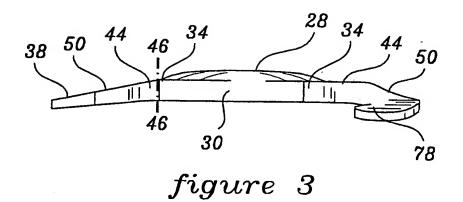
creating an incision in a cornea and lens capsule of an eye, removing a natural lens of said eye, and inserting said intraocular lens in said lens capsule of said eye.

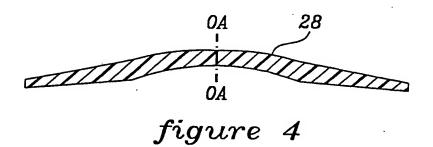


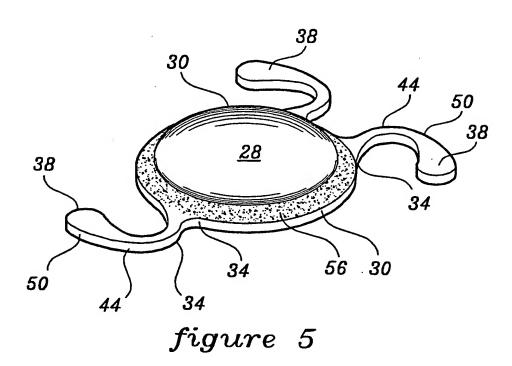


SUBSTITUTE SHEET (RULE 26)

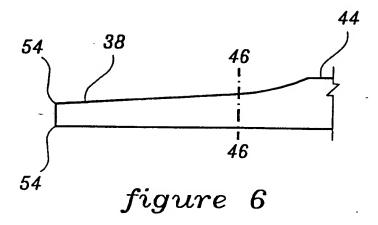
uricumin and amount

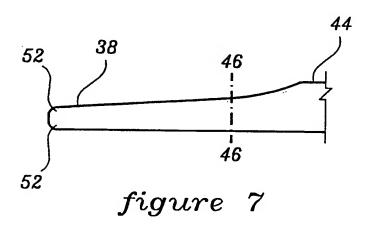


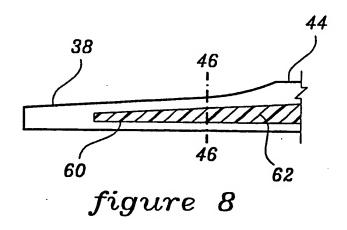




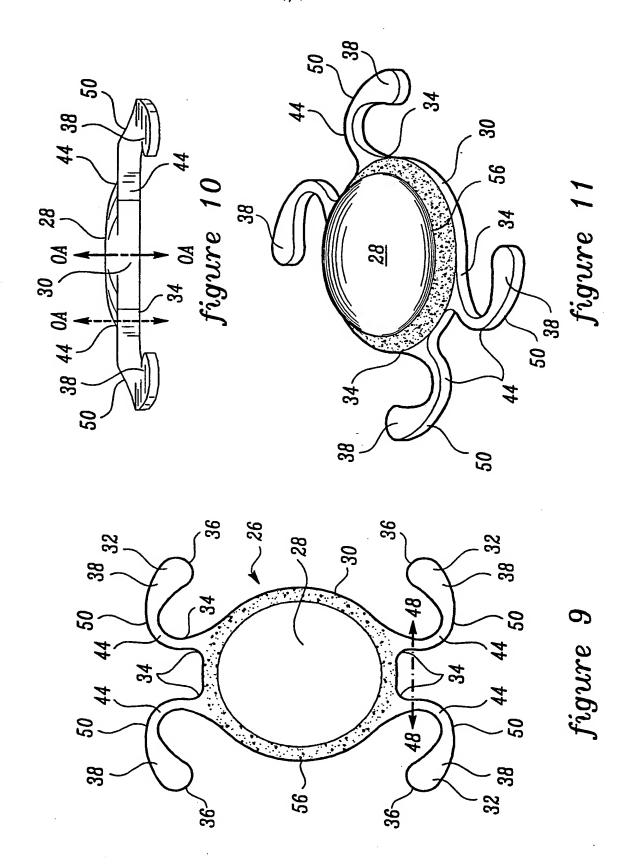
SUBSTITUTE SHEET (RULE 26)







SUBSTITUTE SHEET (RULE 26)



SUBSTITUTE SHEET (RULE 26)

INTERNATIONAL SEARCH REPORT

Inter conal Application No PCT/US 99/24921

			C1/U3 99/24921	
A CLASSI IPC 7	IRCATION OF SUBJECT MATTER A61F2/16			
According to	to International Patent Classification (IPC) or to both national classifi	ication and IPC		
	SEARCHED			
Minimum de IPC 7	ocumentation searched (classification system followed by classifical A61F	ition symbots)		
Documenta	don searched other than minimum documentation to the extent that	such documents are include	d in the fields searched	
Electronic d	ata base consulted during the international search (name of data b	ase and, where practical, se	arch terms used)	
C. DOCUM	ENTS CONSIDERED TO BE RELEVANT			
Cettegory *	Citation of document, with indication, where appropriate, of the re	elevant passages	Relevant	to claim No.
P,X	US 5 928 282 A (NIGAM ALOK) 27 July 1999 (1999-07-27) the whole document		1-7, 9-15, 17-19	
X	US 4 629 460 A (DYER ROBERT L) 16 December 1986 (1986-12-16) column 1, line 9 - line 15 claims; figures		1-3	
X X	US 5 326 506 A (VANDERBILT DAVID 5 July 1994 (1994-07-05) cited in the application column 1, line 14 -column 3, line column 3, line 64 -column 4, line claims; figures -& US 5 217 491 A	e 35	4-6,8 10,16	,
	cited in the application	-/		
X Furth	ner documents are listed in the continuation of box C.	X Patent family mer	nbers are listed in ennex.	
*Special categories of cited documents: "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "I" document which may throw doubte on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "International filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "C" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such document is combined with one or more other such documents, such combination being obvious to a person skilled in the art. "B" document member of the same patent family				
Date of the actual completion of the international search Date of mailing of the international search report 23/03/2000				
	naling address of the ISA European Patent Office, P.B. 5618 Patentiaan 2 Ni 2280 HV Rijswijk Tel. (451-70) 340-2040, Tx. 31 651 epo ni,	Authorized officer Kuehne, H		
	Fax: (+31-70) 340-3016	~	1	

INTERNATIONAL SEARCH REPORT

tnts ional Application No PCT/US 99/24921

		PC1/US 99/24921
	ation) DOCUMENTS CONSIDERED TO BE RELEVANT	
ategory *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A .	US 4 578 078 A (ARKELL JAMES J ET AL) 25 March 1986 (1986-03-25) column 3, line 17 - line 28 column 6, line 56 -column 7, line 8 column 8, line 48 -column 9, line 27 claims; figures 5,6,9,10	1-5,10, 12,15, 17-19
A .	US 5 078 740 A (WALMAN GERALD B) 7 January 1992 (1992-01-07) column 1, line 51 -column 3, line 39 claims; figures 1-4	1-5,10, 12,17-19
A	US 4 504 981 A (WALMAN GERALD B) 19 March 1985 (1985-03-19) claims; figures	1-3
A	US 4 687 485 A (LIM DRAHOSLAV ET AL) 18 August 1987 (1987-08-18) column 1, line 56 -column 2, line 4 column 3, line 2 -column 4, line 38 claims; figures	1-19

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inte onal Application No PCT/US 99/24921

Patent document		Publication		atent family	Publication
cited in search report	l .	date		nember(s)	date
US 5928282	A	27-07-1999	AU	7963498 A	30-12-1998
	••		CN	1236310 T	24-11-1999
			EP	0925044 A	30-06-1999
			MO	9856315 A	17-12-1998
US 4629460	Α	16-12-1986	NONE		
US 5326506	A	05-07-1994	US	5217491 A	08-06-1993
			AT	162066 T	15-01-1998
			AU	649758 B	02-06-1994
			AU	9005991 A	02-07-1992
			CA	2058350 A	28-06-1992
			DE	69128703 D	19-02-1998
			DE	69128703 T	30-04-1998
			EP	0492126 A	01-07-1992
			ES	2110973 T	01-03-1998
			JP	4295353 A	20-10-1992
US 4578078	Α	25-03-1986	AU	564602 B	20-08-1987
			CA	1226402 A	08-09-1987
			. CS	248038 B	15-01-1987
			EP	0091242 A	12-10-1983
			JP	1764870 C	11-06-1993
			JP	4053542 B	26-08-1992
			JP	58185153 A	28-10-1983
			SU	1386017 A	30-03-1988
US 5078740	Α	07-01-1992	NONE		
US 4504981	Α	19-03-1985	US	RE34424 E	26-10-1993
US 4687485	Α	18-08-1987	US	4961746 A	09-10-1990

THIS PAGE BLANK USPION